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EXAMINER	
KWAK, DEAN P	
ART UNIT	PAPER NUMBER
4153	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,564	MAGNALDO ET AL.	
	Examiner	Art Unit	
	Dean Kwak	4153	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/14/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **illumination means** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a **single paragraph** on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "**means**" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because: "Fig. 4a" should be deleted.

Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because of the following informalities: Page 5, Line 11, “i.a” is not clear.

Appropriate correction is required.

Claim Objections

5. Claim 1 is objected to because of the following informalities: Claim line 10, it is unclear what “these" is directed to.

6. Claim 8 is objected to because of the following informalities: Claim line 3 the unit “µl µL.min^{-1}” should be fixed.

7. Claims 9 & 10 are objected to because of the following informalities: Claims lines 4, it is unclear what "+" states.

8. Claim 12 is objected to because of the following informalities: Claim line 2, it is unclear what “this" is directed to.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Lear et al. (US 5,252,486).

Regarding Claim 1, O'Lear et al. disclose a method for analyzing a liquid sample (Abstract) by injecting the latter in a reaction loop (e.g. coil of tubing, Fig. 1 (41), C12/L57-58) coupled with illumination means and detection means, characterized in that it comprises the following steps:

- filling a reaction loop with a minimum volume of the sample to be analyzed (C5/L34-36), this reaction loop sample forming a transparent pipe (C13/L2) with which detection means (e.g. colorimeter, Fig. 1 (49), C12/L68) are coupled,
- injecting a fixed volume of at least one reagent (e.g. color-forming reagent, C12/L39) into the reaction loop,
- detecting levels of filtered light (e.g. 600-850 nm filter, C4/L39) by these detection means,
- discharging the reagents located in the reaction loop (e.g. waste, C12/L30).

Regarding Claims 2-8, O'Lear et al. further disclose the method, wherein:

- a concentration gradient is detected in the reaction loop (see determination of concentration at designated intervals, C4/L9-22);
- the reaction loop is a transparent capillary or a microfluidic channel (e.g. internal diameter of 0.0125 cm, C5/L28);
- the discharge of the reagents located in the reaction loop is performed by means of the remaining sample (C5/L5-7);
- the discharge of the reagents located in the reaction loop is performed by means of the next sample (C12/L28-31);
- the sample flux is not interrupted, which allows continuous analysis (e.g. continuous supply of fresh sample, C12/L31);
- fixed volumes of reagents are successively injected during predefined time intervals (C4/L19-22); and
    - a series of pulses of reagents is produced at flow rates of the order to 10 to 1,000 µL/min (e.g. 0.15 ml/min or 150 µL/min, C5/L34) followed by a waiting time;

Regarding Claim 9, O'Lear et al. further discloses the method, wherein:

- linear detection (e.g. colorimeter, Fig. 1 (49), C12/L68) is performed along the reaction loop.

Regarding Claim 9, with obtained information from the system, it is possible that the recited claim limitations can be achieved.

11. Claims 1, 2, 9, 12 & 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Pollema et al. (US 5,849,592).

Regarding Claim 1, Pollema et al. disclose a method for analyzing a liquid sample (Abstract) by injecting the latter in a reaction loop coupled with illumination means and detection means, characterized in that it comprises the following steps:

- filling a reaction loop with a minimum volume of the sample to be analyzed (C4/L44-47), this reaction loop (e.g. reaction coil, Fig. 4A (RC), C4/L49) sample forming a transparent pipe with which detection means (e.g. flow-through detector, Figs. 1-4 (D), C2/L53) are coupled;
- injecting a fixed volume of at least one reagent (e.g. reagent, (R), C4/L52) into the reaction loop;
- detecting levels of filtered light by these detection means (e.g. colorimeter, Claim 5); and
- discharging the reagents located in the reaction loop (e.g. waste, C12/L30).

Regarding Claim 1, a flow-through detector inherently has a transparent pipe as a part of its property. In addition, in order for a colorimeter to function, it is always used with a filtered light. As evidence, Hach (GB 967,586) discloses a liquid analyzing system utilizing a colourimeter (Fig. 1 (15)) with a colour filter (Fig. 1 (63)) as detection means. Furthermore, it is noted that a liquid analyzing system by means of injection inherently discharges its analyzed samples from the reaction loop. See MPEP § 2112.

Regarding Claims 2 & 9, Pollema et al. further disclose the method, wherein:

- a concentration gradient is detected in the reaction loop (C1/L25-27); and
- linear detection (e.g. colorimeter, potentionmeter, Claims 5 & 6, respectively) is performed along the reaction loop so that it is possible to obtain a space and time plot of the reactions in the set, reaction loop + detection means.

Regarding Claim 9, with obtained information from the system, it is possible that the recited claim limitations can be achieved.

Regarding Claim 12, Pollema et al. disclose a flow-injection analysis system (Abstract) for analyzing a liquid sample comprising:

- a reaction loop (e.g. reaction coil, Fig. 4A (RC), C4/L49) between this sample introduced through an inlet (see valve (MPV) inlet in Fig. 4A) and at least one reagent (e.g. reagent, (R), C4/L52), and
- detection means (e.g. flow-through detector, Figs. 1-4 (D), C2/L53 & colorimeter, potentionmeter, Claims 5 & 6, respectively)), characterized in that the reaction loop consists of a transparent pipe, and
- in that said system comprises a push-syringe (e.g. syringe pump, Figs. 3A & 4A (SP)),
- the outlet (see valve (MPV) in Fig. 4A connecting to the (RC)) of which is connected to the reaction loop allowing doses of said at least one reagent to be delivered into this loop, and
- illumination means with which this reaction loop may be illuminated so that the detection means record levels of light transmitted through said loop after filtering

Regarding Claim 12, a flow-through detector inherently has a transparent pipe as a part of its property. In addition, in order for a colorimeter to function, it is always used with a filtered light. As evidence, Hach (GB 967,586) discloses a liquid analyzing system utilizing a colourimeter (Fig. 1 (15)) with a colour filter (Fig. 1 (63)) as detection means. Furthermore, regarding limitations directed to specific functions of a detector recited in said claim, it is noted that a colorimeter detector can not function without having an illumination means to fully function. Even though Pollema et al. do not

explicitly disclose an illumination means, however, it is inherent property for the detector to function with at least one illumination means. As evidence, Hach (GB 967,586) discloses a lamp (Fig. 1 (60)) as an illumination means to be used with a colourimeter as detection means (Fig. 1 (15)). See MPEP § 2112.

Regarding Claim 16, Pollema et al. disclose all the claim limitations as set forth above. In addition, Pollema et al. disclose the system comprising a peristaltic pump allowing introduction of the sample (C1/L49-50, Figs. 1A-2B (PP)).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 10 & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Lear et al. (US 5,252,486) & Pollema et al. (US 5,849,592) as respectively applied to claim 1 above, respectively, and further in view of Pawliszyn (US 4,940,333).

Regarding Claims 10 & 11, O'Lear et al. & Pollema et al. respectively disclose all the claim limitations as set forth above. However, O'Lear et al. & Pollema et al. respectively fail to disclose a method for analyzing a liquid sample comprising a movable point detector.

Pawliszyn discloses a method for analyzing a liquid, wherein:

- a concentration gradient is detected in the reaction loop (Abstract);
- the reaction loop is a transparent capillary or a microfluidic channel (e.g. capillary, Fig. 9 (51), C9/L41);
- the discharge (e.g. discharge tube, Fig. 10 (77)) of the reagents located in the reaction loop is performed by means of the next sample (C10/L23-26);
- a point detection (e.g. optical fiber, Fig. 10 (79 & 83), C10/L26 & 30) is achieved in a location of the reaction loop so that it is possible to obtain a time plot of the reactions in a location of the set: reaction loop + detection means; and
- a point sensor is used, capable of moving along the reaction loop (C5/L54).

Regarding Claim 11, it is noted that gluing can be unglued to relocate the detector to another position.

O'Lear et al., Pollema et al. and Pawliszyn are analogous because these references are directed to liquid analysis (Abstracts).

It would have been obvious to one of ordinary skill in the art at the time of the respective invention to combine movable point detection means, as taught by Pawliszyn, to the respective liquid analyzers, as taught by O'Lear et al. & Pollema et al., to provide a relocating detector function of optical fibers to study concentration gradient at different positions within the sampling location.

16. Claims 13, 15, 17 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pollema et al. (US 5,849,592) as applied to claim 12 above, and further in view of Pawliszyn (US 4,940,333).

Regarding Claim 13, Pollema et al. disclose all the claim limitations as set forth above. However, Pollema et al. fail to disclose the system comprising a capillary channel.

Pawliszyn discloses a system for analyzing liquid sample (Abstract) comprising:

- a reaction loop (e.g. sample chamber, Figs. 9 (54) & 10 (78), C9/L43 & C10/L25, respectively) between this sample introduced through an inlet (Fig. 9 (60), C9/L48) and at least one reagent (e.g. solvent, Fig. 9 (59)); and
- detection means (e.g. optical fiber, Fig. 10 (79 & 83), C10/L26 & 30);
- characterized in that the reaction loop consists of a transparent pipe (C5/L49); and
- the outlet (e.g. tubing, Fig. 9 (56)) of which is connected to the reaction loop allowing doses of said at least one reagent to be delivered into this loop; and

- illumination means (e.g. LED, Fig. 10 (82), C10/L29) with which this reaction loop may be illuminated so that the detection means record levels of light transmitted through said loop after filtering; and
- the transparent pipe is a transparent capillary or a microfluidic channel (e.g. capillary, Fig. 9 (51), C9/L41);

Pollema et al. and Pawliszyn are analogous because these references are directed to liquid analysis (Abstracts).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a capillary tube, as taught by Pawliszyn, to the liquid analyzers, as taught by Pollema et al., to further take the advantages of using low sample and reagent necessary to carry out the analysis.

Regarding Claim 15, Pawliszyn further discloses the system comprising:

- the detection means comprise two optical fibers (Fig. 10 (79 & 83), C10/L26 & 30) positioned on either side of the reaction loop.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine optical fibers as detection means, as taught by Pawliszyn, to the flow injection analyzer, as taught by Pollema et al., to add different detection properties of optical fibers since each detector has its own detection range.

Regarding Claim 17, Pawliszyn further discloses the system comprising:

- a microvalve (e.g. valve, Fig. 9 (57)) positioned upstream from the point of introduction of the sample into the reaction loop.

Regarding Claim 17, even though the primary reference is silent to the specific valve used, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a microvalve, as taught by Pawliszyn, since the system is directed to analyze liquid in small volumes which requires precise sample and reagent dispersions.

Regarding Claim 18, Pawliszyn further discloses the system comprising:

- a T-shaped branch (e.g. T, Fig. 9 (52)) is respectively connected to the sample inlet, to the push-syringe and to the reaction loop.

Regarding Claim 18, the primary reference states a various required connecting tubing used (C1/L51-52), however, it is silent to the specific shaped branch used thereof. It is well known in the art that the connections can have a variety of shapes of configurations, including T-shaped, C-shaped (semi-circular), square, circular, rectangular, polygonal, etc. The change in configuration of shape of a device is obvious

absent persuasive evidence that the particular configuration is significant. *In re* Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). It would have been obvious to one having ordinary skill in the art at the time of the invention to use a T-shaped branch to connect the sample inlet to the push-syringe in order to increase the efficiency of the flow as well as simplify the arrangement.

17. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pollema et al. (US 5,849,592) as applied to claim 12 above, and further in view of Petro et al. (US 6,584,832).

Regarding Claims 14, Pollema et al. disclose all the claim limitations as set forth above. However, Pollema et al. fail to disclose a detection means comprise a diode array.

Petro et al. disclose a flow-injection analysis system wherein:

- a reaction loop (see around detection cavity, Fig. 2B (131)) between sample introduced through an inlet (e.g. injection port, Fig. 2B (108)) and at least one reagent (e.g. additional injection port, Fig. 2B (108')); and
- in that said system comprises a push-syringe (e.g. syringe pump, C30/L4);
- the outlet (see Fig. 2B tubing post filter (104)) of which is connected to the reaction loop allowing doses of said at least one reagent to be delivered into this loop;

- the detection means comprise a diode array (e.g. photodiode array detector, Fig 2B (130), C21/L27); and
- a peristaltic pump allowing introduction of the sample (C30/L11).

Pollema et al. and Petro et al. are analogous because these references are directed to flow injection analysis (Abstracts).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine diode array as detection means, as taught by Petro et al., to the flow injection analyzer, as taught by Pollema et al., to add different detection properties of a diode array since each detector has its own detection range.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dean Kwak whose telephone number is (571)270-7072. The examiner can normally be reached on M-TH, 7:30 am - 5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Basia Ridley can be reached on (571)272-1453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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16SEP08

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